K133873

APR 0 4 2014

510(k) Summary

Date Prepared: 03-Apr-2014

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Rd, Tel - 011-886-2-2290-3959
Wu-Ku District, New Taipei City, Taiwan Fax - 011-886-2-2299-9076

Official Contact: Winnie Chung
Regulatory Affairs Associate

Proprietary or Trade Name: TriBall Incentive Spirometer

Common/Usual Name: Incentive spirometer

Classification Name: 21CFR 868.5690
BWF - spirometer, therapeutic (incentive)
Class II

Predicate Devices: K781831 – Hudson RCI TriFlo

Device Description:
The Besmed TriBall Incentive Spirometer has a flexible tube and mouthpiece which the patient inhales through. This tube connects to the inspiration port of the unit. The chamber has a series of balls which upon the patient inhaling, creates a vacuum, which causes the balls to rise, they reflect the inspiratory flow rate in cc/sec (600, 900 and 1200).

It is a single patient, multi-use, disposable, non-sterile device.

As a patient improves their respiratory capacity or gets stronger they improve their inspiratory flow rate raises the balls. The principle is to provide the user a visual indicator of their inspiratory flow rate and help them to improve the respiratory function with repeated uses. Incentive spirometers are commonly referred to as "lung exercisers".

The TriBall achieves the therapeutic intent by helping the patient to improve their inspiratory flow rate. It is a relative improvement device that as described offers the patient the "incentive" to improve. This is the identical therapeutic intent of all predicate flow / volume based incentive spirometers.

Indications for Use:
The Besmed Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser.

Intended for single-patient, multi-use in a hospital or home care setting.

Patient Population:
Patients requiring inspiratory exercise.

Environments of use:
Hospital and home care settings

Comparison to Predicates

Attribute	Hudson RCI K781831	Proposed Besmed TriBall
Indications for Use	Intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.	The Besmed Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.
Environments of use	Home care settings and hospitals	Home care settings and hospitals
Prescriptive	Yes	Yes
Patient population	Patients requiring inspiratory exercise	Patients requiring inspiratory exercise
Single patient, multi-use	Yes	Yes
Patient interface	Mouthpiece	Mouthpiece
Basic components	Housing 3 balls Tubing Mouthpiece Gross particulate filter	Housing 3 balls Tubing Mouthpiece Gross particulate filter
Flow / Volume range	600 / 900 / 1200 cc/sec	600 / 900 / 1200 cc/sec
Performance testing	Inspiratory Rate / Volume accuracy 600 – 16.7% 900 – 1.6% 1200 – 11.3% Accuracy specification – not stated	Inspiratory Rate / Volume accuracy 600 – 0.5% 900 – 0.3% 1200 – 0.1% Accuracy specification - +/- 5%
		Age Testing Pre and post- exposure Environmental Testing High / Low and Humidity conditions Drop test

Substantial Equivalence Discussion

Table 1 compares the key features of the proposed Besmed TriBall incentive spirometer with the identified predicate and demonstrates that the device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K781831 – Hudson RCI incentive spirometer.
Discussion – Each device is indicated for use volumetric inspiratory deep breathing positive exerciser.

Technology and construction –
The design, components, shape, size, etc. are equivalent to the predicate – K781831 – Hudson RCI incentive spirometer.
Discussion – The design is a 3 ball system that upon the patient inhaling raises the balls to indicate the volume of inspired air.

Environment of Use –
The environments of use are identical to predicate - K781831 – Hudson RCI incentive spirometer.
Discussion – The environments of use are identical to the predicate K781831 – Hudson RCI incentive spirometer.

Patient Population –
The patient population of patients requiring inspiratory exercise is equivalent to the predicate – K781831 – Hudson RCI incentive spirometer.
Discussion – The patient populations are equivalent to the predicate – K781831 – Hudson RCI incentive spirometer.

Non-Clinical Testing Summary –

Materials:
We have performed ISO 10993 testing on the component materials of the TriBall Incentive spirometer which is considered as External Communicating (Indirect gas pathway) and Surface Contact (direct skin) with the patient which means the following tests were performed.

- Cytotoxicity
- Sensitization
- Intracutaneous / Irritation

Environmental:
The proposed device was exposed to various environmental conditions of high and low temperatures over time and the performance evaluated and compared before and after these tests to confirm that the proposed device met it performance specifications.

Performance Testing including Comparative:
We performed comparative volume accuracy to the predicate and the results demonstrated equivalent (or better) performance demonstrating the proposed device is equivalent to the – K781831 – Hudson RCI incentive spirometer.

Multiple samples of each device were tested multiple times and then evaluated for consistency of performance.

Substantial Equivalence Conclusion -

The proposed device has been found to be substantially equivalent to the predicate. Differences between the proposed device and the predicate do not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

Besmed Health Business Corp
C/O Mr. Paul Dryden, President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K133873

Trade/Device Name: TriBall Incentive Spirometer
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive spirometer
Class: II
Product Code: BWF
Dated: March 5, 2014
Received: March 6, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133873

Device Name
Besmed TriBall Incentive Spirometer

Indications for Use *(Describe)*

The Besmed Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser.

Intended for single-patient, multi-use in a hospital or home care setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K133873

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=001131559 0
Date: 2014.04.03 11:45:44 -04'00'